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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,544	10/26/2001	Steve A. Herweck	ATA-333	2463

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LAHIVE & COCKFIELD, LLP.
28 STATE STREET
BOSTON, MA 02109

EXAMINER

WOO, JULIAN W

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/045,544

Applicant(s)

HERWECK ET AL.

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10-15, 19-21, 23, 24, 26-36, 38, 39, 41-54 and 56 is/are rejected.
- 7) ☒ Claim(s) 8, 9, 16-18, 22, 25, 37, 40, 55, and 57 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/27/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-7, 13-15, 19-21, 23, 24, 26-28, 30-32, 35, 36, 38, 39, 41-46, 48-51, and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Buselmeier (3,826,257). Buselmeier discloses, in figures 1-5, a body fluid cartridge exchange platform (10) or access device, where the device includes, inter alia, a hollow tubular platform housing (15) with first and second ends (at 15b and 15c), an arcuate flow path or channel, and respectively first and second openings at the ends; tubular cartridge inserts (17) or cartridges insertable and removable through the first and second openings and be used for drug delivery, each having a flow path, a channel, first and second channel ports, or lumens; first and second hollow leg members (16) with first and second ports and multiple lumens in fluid communication with the platform and with organs; and a locking mechanism (e.g., ties according to col. 5, line 63 to col. 6, line 2) for each of the tubular cartridge inserts; where each of the cartridge tubular inserts provides a flow path having a diameter that varies from a diameter relatively greater than an internal diameter of the first hollow leg member to substantially the same diameter as the internal diameter of the first hollow leg member (see element 17 in figures 4 and 5), and where the first and

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second legs penetrate the skin of a patient (see figures 1 and 2) or minimally invasively implanted in a patient.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claims 10, 33, 53, and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buselmeier. Buselmeier discloses the invention substantially as claimed, but does not disclose first and second legs, each having a diameter of less than 10mm; nor does Buselmeier disclose a cartridge insert tool. However, Buselmeier discloses, in col., 5, line 63 to col. 6, line 2, that the size of an implant, including its legs, can be of a "suitable size" in order to match the sizes of the lumen of the artery and vein selected. Thus, it would have been a matter of design choice to size each of the first

and second legs at a diameter of less than 10mm. The choice would be dependent upon the sizes of the lumen of the artery and vein selected. It would also be obvious to one having ordinary skill in the art at the time the invention was made, to apply a common, surgical tool, such as a forceps, as a cartridge insert tool. Forceps would provide a convenient means to grip and manipulate a cartridge for insertion and removal through a hollow tubular platform housing.

5. Claims 11, 34, and 52 rejected under 35 U.S.C. 103(a) as being unpatentable over Buselmeier in view of Schulte (3,853,126). Buselmeier discloses the invention substantially as claimed, but does not disclose first and second legs each comprising a microporous cell penetrable cuff disposed at a sub-dermal end of the first and second hollow leg members when implanted in a patient. Schulte teaches, in col. 1, lines 55-62 and col. 4, lines 30-50, microporous cell penetrable cuffs (60, 61) disposed at a sub-dermal end of first and second hollow leg members implanted in a patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Schulte, to apply cuffs to the first and second hollow leg members. Such cuffs on the legs would provide a bar to the penetration of organisms, which might be sources of infection.

6. Claims 12, 29, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buselmeier in view of Santerre et al. (5,798,115). Buselmeier discloses the invention substantially as claimed, but does not disclose a bioactive coating disposed on at least a portion of the flow path between the first and second hollow leg members and through the tubular cartridge insert. Santerre et al. teach

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bioactive coatings for various implants. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Santerre et al., to include bioactive coating disposed on at least a portion of the flow path of Buselmeier's device. Such a coating would reduce infections caused by the presence of access devices in a patient's body.

Allowable Subject Matter

7. Claims 8, 9, 16-18, 22, 25, 37, 40, 55, and 57 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination discloses a body fluid cartridge exchange platform or access device with, inter alia, a housing having first and second openings, first and second hollow leg members extending from the housing, and cartridge inserts or cartridges, where an external communicating passageway is coupled to one of the openings, where a locking mechanism on a cartridge insert comprises a flexible tab, where at least one marking is disposed on at least one of the cartridge insert and the platform housing, where the first leg extends in a staggered and divergent manner from the second leg with respect to the housing, where a cartridge has at least one external passage in communication with the channel of the cartridge, and where the housing has a generally oval cross-section.

Response to Amendment

9. Applicant's arguments filed on December 29, 2003 have been fully considered but they are not persuasive.

The rejections of claims under on 35 U.S.C. 112 are hereby withdrawn.

With respect to arguments regarding the rejection of claims under 35 U.S.C. 102 and 103 and based on the reference Buselmeier: Buselmeier does disclose bi-directional installation and bi-directional removal of the tubular cartridge (17) at first and second openings (15b and 15c), where the cartridge has a channel completing a flow path (R as seen in fig. 5) between first and second passages through first and second ports (16.1, 16.2) and where the cartridge (17, not 13 as argued) of an access device sealingly engages or tightly grips an interior of the housing (15) of the access device.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached at (703) 308-2496.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703) 308-0858. The official FAX number is (703) 872-9302.



Julian W. Woo
Primary Examiner

March 18, 2004